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PRIORITY DOCUMENT

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PATENT APPLICATION NO: PI 2002 2342

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By authority of the REGISTRAR OF PATENTS

ABDUL RAHMAN RAMLI

(CERTIFYING OFFICER)

17 December 2003



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Ministry of Domestic Trade and Consumer Affairs Malaysia Intellectual Property Division.

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CERTIFICATE OF FILING

APPLICANT

: MOO YOON NGEK

APPLICATION NO.

PI 20022342

REQUEST RECEIVED ON: 21/06/2002

FILING DATE

: 21/06/2002

AGENT'S/APPLICANT'S

: PIP/0813/IPPF/02/LCH/YAN

FILE REF.

Please find attached, a copy of the Request Form relating to the above application, with the filing date and application number marked thereon in accordance with Regulation 25(1).

Date: 10/07/2002

(SHAMSIAH BTI KAMARUDDIN)

for Registrar of Patents

To:

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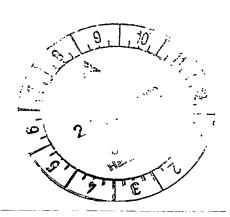
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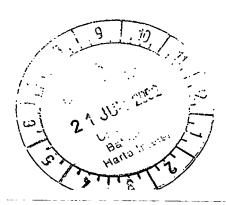
III.	INVENTOR:
	Applicant is the inventor: Yes X No
	Name of inventor Address:
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	A statement justifying the applicant's right to the patent Accompanies this Form:
	Yes No x
Additio	nal Information (if any)
IV.	AGENT OR REPRESENTATIVE:
	Applicant has appointed a patent agent in accompanying Form No17
	Yes X
	Agent's Registration No: PA/99/0077 Applicants have appointed: LOK CHOON HONG To be their common representative.
v.	DIVISIONAL APPLICATION:
	This application is a divisional application
	The benefit of the filing date priority date
	Of the initial application is claimed in as much as the subject- matter of the present application is contained in the initial application identified below:
Initial	Application No.:
Date of	filing of initial application;
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VI.	DISCLOSURES TO BE DISREGARDED FOR PRIOR ART PURPOSE:					
	Additional information is contained in supplemental box:					
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	Date of disclosure:					
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VIII CHECK LIST						
VIII CHECK LIST						
A. This application contains the following:						
1. Request 2. Description 3. Claim 4. Abstract 5. Drawings Total	4 6 2 1 1	sheets sheets sheet sheets sheets				
This Form, as filed, is accompanied by the items ch	necked	below:				
(a) signed Form No. 17		×	- :			
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(d) statement that certain disclosures be disregarded						
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(g) other documents (specify)			_			
IX. SIGNATURE LOK CHOON HONG	20 6 (Date					
Agent's Registration No.: PA/99/0077						
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Precision contoured EXO/ENDOcervical cell sampler

Field of Invention

The invention relates to a specific device for collecting representative cell samples from exocervix and endocervix for cytological microscopic examination, particularly for the purpose of pre-malignant and malignant diagnosis.

10 Background of the Invention

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Occurrence of uterine cervical cancer is high among women and the rate has been increasing. The disease becomes the main cause of cancer death among women in Malaysia. Of vital important, women are advised to have periodical medical pelvic examinations for early detection and prevention of uterine cervical cancer.

Many devices have been invented for sampling of representative cells from the uterine endocervix and exocervix for the purpose of pre-malignant and malignant diagnosis. Such devices are generally having an elongated stem with a portion at one end, which is designed as a swab, spatula or a brush. However, conventional been reported from these have techniques. The swab technique has the disadvantages that the stick may break when abrasive force is applied to enable specimen sampling and extra time-consuming step is required to examine the mixing of desired and undesired cells on a microscope slide. In addition the cotton buds swab stick is also unsatisfactory in retaining and transferring of cellular samples due to its rather tightly-wound and very absorbent ball-like surface. It has also a very limited contact with the exocervix.

The spatula technique enables cell sampling even from deeper cell layers, however, such device may cause post-exam bleeding or abrasion at the sampling spot. In addition the wooden or plastic spatulas are too stiff and rigid to provide an even and thorough scraping of the unevenly contoured uterine cervix. It is also less efficient in transferring the cellular samples onto the glass slides due to its inflexible L-shaped end portion.

Overly blood-stained and a fair number of critical cervical cells are being trapped in between the bristles and hence do not get transferred fully onto the glass slides and therefore are wasted and lost for diagnosis. The brush device has also a very limited contact with the exocervix.

Summary of the Invention

The primary object of this invention is to provide a new and improved cell sampler to collect representative cell samples from the exocervix and endocervix for cytological microscopic examination. It involves only a simple "one-step" operation where a single insertion into the cervical canal can obtain both exocervical and endocervical cell samples.

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Another object of this invention is to provide a cell sampler that holds securely at the exocervix and prevent excessive penetration into the internal os.

30 Still another object of this invention is to provide a cell sampler having an endocervical contact portion that is safe in use, thereby provides more comfort and less abrasive when making a complete 360 DEG rotational sweeping-up of all the representative cells.

Yet another object of this invention is to provide a cell sampler that is capable of collecting cells from deep inside body cavities due to the semi rigid vertical reach of the endocervical contact portion.

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A further object of this invention is to provide a cell sampler that allows combined yet separated cell samples from both exocervical and endocervical regions with just a single swipe onto a microscope slide where these cellular portions are clearly visible.

A still further object of this invention is to provide a cell sampler having a slightly thickened-handle to enhance better finger grip and optimal rotational manipulation.

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These and further objects, features and advantages of the present invention will become apparent from the following description when taken in connection with the accompanying drawings which, for purposes of illustration only, show the preferred embodiment in accordance with the present invention.

Brief Description of the Drawings

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FIG. 1 is a perspective view of the present cell sampler for sampling purpose.

FIG. 2 is a perspective view of the present cell sampler for spreading purpose.

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FIG. 3 illustrates the transfer of samples onto a microscope slide.

FIG. 4 illustrates the rotational mechanism of the vertical contact portion of the present cell sampler.

Detailed Description of the Invention

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With figure 1, the drawing shows reference to the embodiment comprises an elongated and rounded stick-shaped stem (1) having a slightly thickened handle means (2) enhance better finger grip bottom end to and optimal rotational manipulation. At the top end of said stem (1) is connected to an abrading means (3). The said abrading means (3) comprises a connecting means (4) and a functional L-shaped cell collecting means (5). The functional L-shaped cell collecting means (5) comprising of a vertical ENDOcervical contact portion (6) therein to aid in insertion of said cell sampler into the endocervix and configured to scrape cytology cell samples onto its surface when said cell sampler rotated; and a horizontal EXOcervical contact portion (7) therein to aid in hugging the exocervix and scraping cytology cell samples onto its surface when said cell sampler is rotated.

20 The said vertical endocervical contact portion (6) connected to the horizontal exocervical contact portion (7) by attachment means, preferably a predetermined, semi-tightened ball joint thus allowing the said vertical contact portion to has a 90 degree free moving angle with the respect to the 25 horizontal exocervical contact portion (7) as shown in figure The vertical endocervical contact portion (6) can stay critically while performing its upright cell rotational scraping function and also enable to made instantly collapsible to a horizontal position onto microscope slide with just very slight finger pressure thus accomplishing its 30 designed objective excellently of spreading the exo/endocervical cells speedily, smoothly and easily onto a microscope slide without the slightest hindrances. attachment means also could be any fasteners, screws, snaps,

clamps, clips, nuts or other such equivalents that could used to secure one surface to another and rotational movements with respect to the horizontal exocervical contact portion (7) are allowed.

The connecting means (4) having one end which is connected to said stem (1) is rounded in cross sectional shape and the other end is a flattened end. Supported one top of the said flattened end is said functional L-shaped cell collecting means (5). The said flattened end of the connecting means (4) comprising of a supporting protrusion (8) at one edge of said flattened end and a retaining protrusion (9) at the other edge of said flattened end. The said EXOcervical contact portion (7) is attached to the supporting protrusion (8) of said connecting means (4).

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The functional L-shaped cell collecting means (5) is coated with resilient material such as sponge, foam, fibre, silicon, PVC film, rubber, soft plastics and the like, thereby provide more comfort and less abrasive, yet direct and gently hugging to the critical transformation zone (T-zone), thereby allowing a thorough and complete 360 DEG rotational sweeping-up of all the truly representative cells. The retaining protrusion (9) of said connecting means (4) being configured to prevent excessive penetration of said cell sampler into the endocervix and lend resistance to the collapsible of said vertical ENDOcervical contact portion (6).

Figure 2 shows a flattened portion of EXOcervical and ENDOcervical contact portions. After a smear sample has been taken from the cervical canal, the said cell sampler is withdrawn from the cervix and the vertical ENDOcervical contact portion (6) will immediately be bent and collapsed on top of a microscope slide (10) as shown in figure 3, becoming

a horizontal, straight and flat spreading strip to be gently swept across the full length of the microscope slide (10), demonstrating clearly a combined yet separated cellular portions from both the exocervical and endocervical regions.

The invention is advantageously for use in a simple "one-step" operation involving only a single insertion for sampling cells from exocervix and endocervix and obtain representative cells from both regions to be included on the same microscope slide.

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It is to be understood that the present invention may be embodied in other specific forms and is not limited to the sole embodiment described above. However modification and equivalents of the disclosed concepts such as those which readily occur to one skilled in the art are intended to be included within the scope of the claims which are appended thereto.

Claims

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- 1. A cell sampler comprising of:
- a stick-shaped stem having a top and a bottom end;
- a collecting means in a L-shaped configuration for collecting smear sample from cervical canal, whereby said collecting means having a flexible construction which can be bent and flattened into a straight shape for easily spreading said sample; and
- 10 a connecting means connected said collecting means to the top end of said stick-shaped stem.
 - 2. The cell sampler as claimed in claim 1, wherein said L-shaped collecting means comprising of a horizontal contact portion for hugging the exocervix and scraping cytology cell samples onto its surface when said cell sampler is rotated; and a vertical contact portion to aid in insertion of said cell sampler into the endocervix and configured to scrape cytology cell samples onto its surface when said cell sampler is rotated.
 - 3. The cell sampler as claimed in any claim 1 to 2, wherein said connecting means further comprising one end which is connected to said top of the said stick-shaped stem rounded in cross sectional shape and the other end in a flattened shape end.
 - 4. The cell sampler as claimed in claim 3, wherein said flattened end of said connecting means, comprising of a supporting protrusion at one edge of said flattened end to support said horizontal contact portion of said collecting means and a retaining protrusion at the other edge of said flattened end to prevent excessive penetration of said cell sampler into the endocervix and lend resistance to the

collapsible of said vertical contact portion of said cell collecting means.

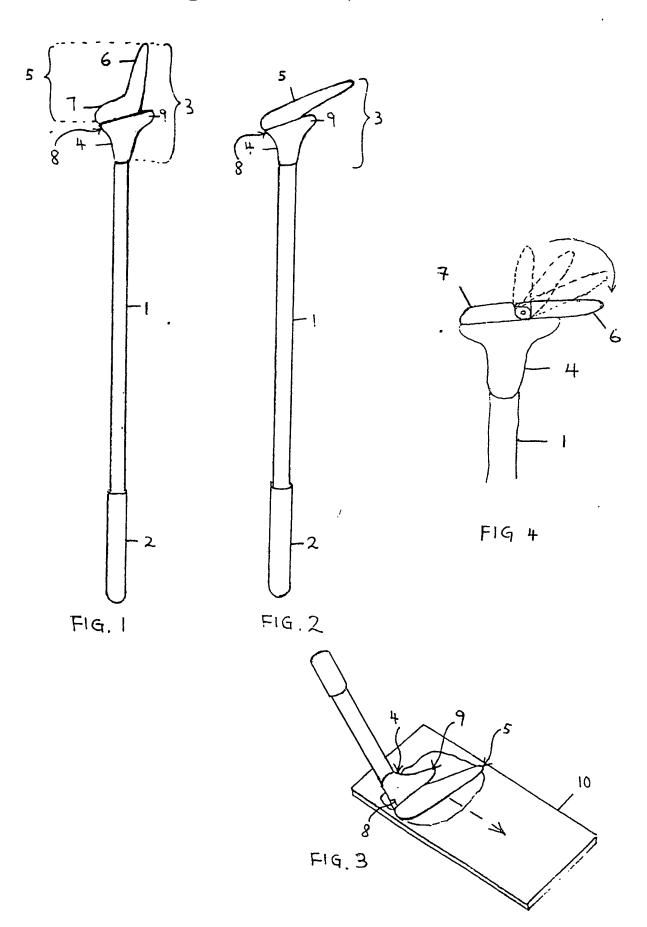
- 5. The cell sampler as claimed in any claim 1 to 4, wherein said stick-shaped stem is elongated and rounded in shape.
 - 6. The cell sampler as claimed in any claim 1 to 5, wherein said bottom end of the stick-shaped stem is thickened to form a handle means for better finger grip and optimal rotational manipulation.

- 7. The cell sampler as claimed in any claim 1 to 6, wherein said connecting means is a narrow and flat piece.
- 8. The cell sampler as claimed in any claim 1 to 7, wherein said cell collecting means is coated with resilient material such as sponge, foam, fibre, silicon, PVC film, rubber, soft plastics and the like.
- 9. The cell sampler as claimed in any claim 1 to 8, wherein said vertical contact portion is connected to the horizontal contact portion by an attachment means.
- 10. The cell sampler as claimed in claim 9, wherein said attachment means could be the semi-tightened ball joint, any fasteners, screws, snaps, clamps, clips, nuts or other such equivalents.

Abstract

Precision contoured EXO/ENDOcervical cell sampler

An L-shaped, precision contoured EXO/ENDOcervical cell sampler for collecting representative cells is invented for premalignant and malignant diagnosis. The said cell sampler comprises of an elongated and rounded stick-shaped stem with a slightly thickened handle means at one end, and a flattened connecting means having two protrusions at the other end. An 10 L-shaped configuration at the root of said connecting means one vertical ENDOcervical contact portion horizontal EXOcervical contact portion, which directly hug to the transformation zone thereby allowing a thorough complete 360 DEG rotational sweeping-up of all the truly 15 representative cells. When said cell sampler is withdrawn from the cervix, the vertical ENDOcervical contact portion subsequently bent and both the EXO- and ENDOcervical portions across a microscope slide for cytological swept microscopic examination. 20



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